

(b) *Sponsor*. See No. 042976 in § 510.600 of this chapter.

(c) *Limitations*. Food or feed from GTC-155-92 goats is not permitted in the food or feed supply.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

Sec.

529.40 Albuterol.

529.56 Amikacin.

529.400 Chlorhexidine tablets and suspension.

529.469 Competitive exclusion culture.

529.536 Detomidine.

529.1003 Flurogestone acetate-impregnated vaginal sponge.

529.1030 Formalin.

529.1044 Gentamicin sulfate in certain other dosage forms.

529.1044a Gentamicin sulfate intrauterine solution.

529.1044b Gentamicin sulfate solution.

529.1115 Halothane.

529.1150 Hydrogen peroxide.

529.1186 Isoflurane.

529.1660 Oxytetracycline.

529.1940 Progesterone intravaginal inserts.

529.2150 Sevoflurane.

529.2464 Ticarcillin powder.

529.2503 Tricaine methanesulfonate.

AUTHORITY: 21 U.S.C. 360b.

SOURCE: 40 FR 13881, Mar. 27, 1975, unless otherwise noted.

§ 529.40 Albuterol.

(a) *Specifications*. A net weight of 6.7 grams of formulated albuterol sulfate is supplied in a pressurized aluminum canister within an actuator system equipped with a detachable nasal delivery bulb.

(b) *Approvals*. See No. 000010 in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(c) *Special considerations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(d) *Conditions of use*—(1) *Amount*. Each valve actuation (puff) of the device delivers 120 micrograms (mcg) of albuterol sulfate. One dose is three (3) puffs, totaling 360 mcg.

(2) *Indications for use*. For the immediate relief of bronchospasm and bronchoconstriction associated with reversible airway obstruction in horses.

(3) *Limitations*. Not for use in horses intended for food.

[67 FR 7072, Feb. 15, 2002]

§ 529.56 Amikacin.

(a) *Specifications*. Each milliliter (mL) of solution contains 250 milligrams of amikacin as amikacin sulfate.

(b) *Sponsors*. See Nos. 000856 and 059130 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount*. Administer 2 grams (8 mL) diluted with 200 mL of sterile physiological saline by intrauterine infusion daily for 3 consecutive days.

(2) *Indications for use*. For treating genital tract infections (endometritis, metritis, and pyometra) in mares caused by susceptible organisms including *Escherichia coli*, *Pseudomonas* spp., and *Klebsiella* spp.

(3) *Limitations*. Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 17339, Mar. 29, 2011]

§ 529.400 Chlorhexidine tablets and suspension.

(a) *Specification*. Each tablet and each 28-milliliter syringe of suspension contain 1 gram of chlorhexidine dihydrochloride.¹

(b) *Sponsor*. See No. 000856 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount*. Place 1 or 2 tablets deep in each uterine horn; or infuse a solution of 1 tablet dissolved in an appropriate amount of clean boiled water; or infuse one syringe of suspension into the uterus.¹

(2) *Indications for use*. For prevention or treatment of metritis and vaginitis in cows and mares when caused by pathogens sensitive to chlorhexidine dihydrochloride.¹

(3) *Limitations*. Prior to administration, remove any unattached placental membranes, any excess uterine fluid or debris, and carefully clean external

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

Food and Drug Administration, HHS

§ 529.1030

genitalia. Use a clean, sterile inseminating pipette for administering solutions and suspensions. Treatment may be repeated in 48 to 72 hours.¹

[43 FR 10705, Feb. 23, 1979]

§ 529.469 Competitive exclusion culture.

(a) *Specifications.* Each packet of lyophilized culture contains either 2,000 or 5,000 doses in frozen pellets to be reconstituted for use.

(1) For 2,000-dose packet, add contents of one 2,000-dose packet of reconstitution powder to 490 milliliters of deionized water. Mix. Add contents of one 2,000-dose packet of lyophilized culture. Mix thoroughly.

(2) For 5,000-dose packet, add contents of one 5,000-dose packet of reconstitution powder to 1,250 milliliters of deionized water. Mix. Add contents of one 5,000-dose packet of lyophilized culture. Mix thoroughly. Allow to stand for 45 minutes before use. Use within 5 hours of reconstitution.

(b) *Sponsor.* See No. 032761 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use. Chickens*—(1) *Amount.* Apply 25 milliliters of reconstituted culture as a topical spray on each tray of 100 chicks (0.25 milliliter per chick).

(2) *Indications for use.* For early establishment of intestinal microflora in chickens to reduce *Salmonella* colonization.

(3) *Limitations.* Administer as soon as possible after hatch, preferably at less than 1 day of age. Expose chicks to light for at least 5 minutes after spray treatment to encourage preening for oral uptake of the organisms. Provide access to feed and water as soon as possible after treatment. Do not administer antibiotics to treated chickens.

[63 FR 25164, May 7, 1998]

§ 529.536 Detomidine.

(a) *Specifications.* Each milliliter of gel contains 7.6 milligrams (mg) of detomidine hydrochloride.

(b) *Sponsor.* See No. 052483 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 0.018 mg per pound

(mg/lb) (0.040 mg/kilogram (kg) sublingually.

(2) *Indications for use.* For sedation and restraint.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Do not use in horses intended for human consumption.

[75 FR 21163, Apr. 23, 2010, as amended at 76 FR 16533, Mar. 24, 2011]

§ 529.1003 Flurogestone acetate-impregnated vaginal sponge.

(a) *Specifications.* Each vaginal sponge contains 20 milligrams of flurogestone acetate.

(b) *Sponsor.* See No. 000014 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Indications for use.* For synchronizing estrus/ovulation in cycling adult ewes during their normal breeding season.

(2) *Limitations.* Using applicator provided, insert sponge into ewe's vagina 13 days before desired start of breeding. For intravaginal use in sheep only. Do not use in young ewes that have not had lambs. Use plastic or rubber gloves when handling large numbers of sponges to minimize exposure to drug. Do not leave sponge in the vagina for more than 21 days. Ewes must not be slaughtered for food within 30 days of sponge removal.

[49 FR 45420, Nov. 16, 1984]

§ 529.1030 Formalin.

(a) *Specifications.* Formalin is an aqueous solution containing approximately 37 percent by weight of formaldehyde gas, U.S.P.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) Nos. 049968, 050378, and 067188 for use as in paragraphs (d)(1)(iii), (d)(1)(iv), (d)(1)(v), (d)(2)(iii), (d)(2)(iv), (d)(2)(v), and (d)(3).

(2) No. 051212 for use as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(2)(i), (d)(2)(ii), and (d)(3).

(c) [Reserved]

(d) *Conditions of use.* It is added to environmental water as follows:

(1) *Indications for use.* (i) Select finfish. For control of external protozoa *Ichthyophthirius* spp., *Chilodonella*